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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RAE, CHARLESWORTH E	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,151	ZHONG ET AL.	
	Examiner	Art Unit	
	Charleswort Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-39 are currently pending and are the subject of this Office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21,and 38-39 drawn to an injectable formulation comprising a) a chemical ablation agent in an amount effective to cause tissue necrosis, and b) a biodisintegrable visocosity adjusting agent in an amount effective to render the formulation highly viscous, wherein said injectable formulation is a sterile injectable formulation, classified in class 424, subclass 463. If this Group is elected, then the below summarized Species Election is also required.

II. Claims 22-26, and 36-37 drawn to a method of treatment comprising injecting the injectable formulation of any of claims 1-21 into the tissue of a subject, classified in class 606, subclass 9+. If this Group is elected, then the below summarized Species Election is also required.

III. Claim 27-32, drawn to a prostatic ablation formulation comprising a prostatic ablation agent selected from free-radical generating ablation agents, oxidizing ablation agents and tissue fixing ablation agents, classified in class 606, subclass 4+. If this Group is elected, then the below summarized Species Election is also required.

IV. Claim 33-35, drawn to a system for the chemical ablation of tissue, said system comprising:

a) an injectable formulation comprising: I) a chemical ablation agent in an amount effective to cause tissue necrosis, and ii) a biodisintegrable viscosity adjusting agent in an amount effective to render the formulation highly viscous; and

b) an apparatus for transcutaneously inserting said dosage form into said tissue, classified in class 607, subclass 92. If this Group is elected, then the below summarized Species Election is also required.

Inventions I and III are directed to related products in that invention I and and invention III comprise ablation agents. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope; i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are comprised of materially different ingredients. For example, invention I is comprised of a) a chemical ablation agent in an amount effective to cause tissue necrosis, and b) a biodisintegrable visocosity adjusting agent in an amount effective to render the formulation highly viscous, while invention III is comprised of ablation agents. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions II and IV are directed to related methods of using an injectable formulation comprising a) a chemical ablation agent in an amount effective to cause tissue necrosis, and b) a biodisintegrable viscosity adjusting agent. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct in view of the fact that invention II can have a materially different mode of operation as compared with invention IV. For example, invention II may be practiced by injecting the injectable formulation via a non-transcutaneous route i.e. through a vein. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I/III and II/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, inventions 1 and III may be practiced by another materially different process of using these products. For example, inventions I and III may be practiced by a materially different method comprising administering said products as a transdermal patch by employing nanotechnology.

Because inventions I-IV are independent or distinct for the reasons given above coupled with the fact that a search is required for each group, restriction for examination purposes is proper. While Groups I-IV can be identically classified under U.S. Patent Classification guidelines, to search them together would present an undue search burden on the Examiner due to the extensive databases of patent and non-patent literature that would have to be searched in view of the divergent subject matter encompassed by the different groups. Thus, Groups I-I V have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Election of Species regarding Groups I-IV

This application contains claims directed to more than one species of the generic inventions that would require an unduly extensive and burdensome search by the examiner if all the claimed species were examined together.

The generic inventions encompass multiple species of chemical ablation agents. For example, the generic invention encompass the following chemical ablation species: a) osmotic-stress generating agent b) organic ablation agent, c) salt, and d) ethanol. Each of the above specie represents a different class of pharmaceutical agents. The species are independent or distinct because the agents possess different pharmaceutical properties. In view of the undue search burden that will be created by the multiplicity of chemical compounds encompassed by these claims, applicant is required to elect one specie from the above listed chemical ablation agents as appropriate for examination purposes.

If applicant elects invention III, then applicant is only required to elect an ablation agent from the following list (instead of from the above list): e) free-radical generating ablation agent, f) oxidizing ablation agent, and g) tissue fixing ablation agent. For example, if applicant elects invention III, then applicant may elect e) free-radical generating ablation agent, or f) oxidizing ablation agent, or g) tissue fixing ablation agent.

Further, applicant may also elect two or more chemical ablation agents from the above "a-d" list of chemical ablation agents if the elected injectable formulation comprises two or more chemical ablation agents (e.g. claim 20).

Additional Election of Species regarding Groups I-IV

The generic inventions encompass multiple species of biodisintegrable viscosity adjusting agents, including the following:

i) polysaccharide, ii) polypeptide, iii) gelatin, vi) collagen, v) polymer. The species are independent or distinct because each specie represents a different pharmaceutical agent. In view of the undue search burden that will be created by the multiplicity of chemical compounds encompassed by these claims, applicant is required to elect one specie from the above listed chemical ablation agents as appropriate for examination purposes.

If applicant elects polysaccharide, then applicant is further required to elect a single specific polysaccharide from the below list for purposes of examination:

i) methylcellulose, ii) hydroxymethylcellulose, iii) hydroxypropyl cellulose, iv) hydroxypropyl methyl cellulose, v) methylhydroxycellulose, vi) hydroxypropyl cellulose,

vii) hydroxypropyl methyl cellulose, viii) methylhydroxyethylcellulose, ix) methylhydroxypropylcellulose, x) carboxymethyl cellulose and its salts, xi) hydroxycarboxymethylcellulose and its salts, xii) carboxymethylhydroxyethylcellulose and its sats, xiii) alginic acid and its salts, xiv) hyaluronic acid and its salts, xv) carageenan, xvi) chitosan, xvii) xanthan gum, xviii) guar gum, xix) gum Arabic, xx) gum karaya, xxi) gum ghatti, xxii) konjac and xxiii) gum tragacanth.

If applicant elects polymer, then applicant is further required to elect a single specific polymer from the below list of polymers for purposes of examination:
i) carboxyvinyl polymer, ii) polyvinylpyrrolidone, iii) polyacrylic acid, iv) polyacrylamide, v) polyacilic acid/acrylamide copolymer, vi) polyethylene oxide, vii) polypropylene oxide, viii) poly(ethylene oxide-propylene oxide), ix) polymetaphosphate, x) polyethylenamine, xi) polypyrriidene, xii) salts thereof.

Further, applicant may also elect two or more viscosity adjusting agents from the above lists of viscosity adjusting agents as appropriate if the elected injectable formulation comprises two or more chemical ablation agents (e.g. claim 19).

Additional Election of Species regarding Group I

The generic invention encompasses multiple species of sub-formulations. For example, the generic invention encompasses the following injectable formulations species:
a) non-imaging contrast agent containing, and b) imaging contrast agent containing formulations.

The species are independent or distinct because each specie exhibit different pharmaceutical characteristics. In view of the undue search burden that will be created by the multiplicity of imaging contrast agents encompassed by these claims, applicant is required to elect either a) non-imaging contrast agent formulation, or an imaging contras agent containing injectable formulation for examination purposes.

If applicant elects an imaging contrast agent containing injectable formulation, then applicant is further required to elect a single specific contrast agent from the below list for examination purposes; namely: i) MRI imaging contrast agent, or ii) ultrasonic imaging contrast agent without solid particles, or iii) ultrasonic imaging contrast agent comprising solid particles.

Additional Election of Species regarding Groups I and II

The generic inventions encompass multiple species of crosslinking agents, including the following: a) ionically crosslinkable polymer, and b) non-ionically crosslinkable polymer, and c) non-polymer crosslinking agent. The species are independent or distinct because each specie represent a different pharmaceutical agent. In view of the undue search burden that will be created by the multiplicity of chemical compounds encompassed by these claims, applicant is required to elect one specie from the above listed chemical ablation agents as appropriate for examination purposes. Applicant is required to elect a single specie of crosslinking agents from the above list for examination purposes e.g. a) ionically crosslinkable polymer.

If applicant elects the ionically crosslinkable polymer species, then applicant is further required to elect a single specific ionically crosslinkable polymer for examination purposes e.g. alginate polymer.

The above species are distinct as they represent different chemical and pharmaceutical agents. The divergent subject matter, coupled with the fact that the species have acquired a different status in the art, creates a search burden on the examiner. In view of the undue search burden that will be created by the multiplicity of chemical ablation agents, biodisintegrable viscosity adjusting agents, crosslinking agents, and imaging contrast agents.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 27, and 33 are considered generic to the above listed species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the

automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

16 December 2006
CER

Ardin H. Marschel 12/18/06
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SUPERVISORY PATENT EXAMINER